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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/816,289	03/23/2001	Carl R. Merrill	PNC-001	6112

21874 7590 11/03/2003

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EXAMINER

GUCKER, STEPHEN

ART UNIT	PAPER NUMBER
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1647

DATE MAILED: 11/03/2003

13

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/816,289

Applicant(s)

Merrill et al.

Examiner

Stephen Buckle

Group Art Unit

1647

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- ☒ Responsive to communication(s) filed on 7/21/03
- ☐ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 1 1; 453 O.G. 213.

Disposition of Claims

- ☒ Claim(s) 1-26 is/are pending in the application.
- Of the above claim(s) 2, 9-26 is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☒ Claim(s) 1 & 3-8 is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
 - ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been received.
 - ☐ received in Application No. (Series Code/Serial Number) _____.
 - ☐ received in this national stage application from the International Bureau (PCT Rule 1 7.2(a)).

*Certified copies not received: _____

Attachment(s)

- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
- ☐ Interview Summary, PTO-413
- ☐ Notice of Reference(s) Cited, PTO-892
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Other _____

Office Action Summary

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Response to Amendment

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

2. Any objections or rejections made in a previous Office Action that are not herein reinstated have been withdrawn.

3. Claims 1 and 3-8 are rejected under 35 U.S.C. 102(b) as being anticipated by Gizurarson et al. (US 5,942,237, "Gizurarson"). Gizurarson teaches methods employing diphtheria toxoid given intranasally to mammals with adjuvants as initial immunizations and booster vaccinations (column 5, line 65 to column 6, line 8; column 6, lines 41-64; and column 7, lines 30-50).

Administration to humans is contemplated (column 1, lines 8-13) along with the optional use of propellant (column 5, lines 1-22 and claim 18). Also see the abstract and claims 4, 8, and 10-11.

Applicant's arguments filed 7/21/03 have been fully considered but they are not persuasive because Applicant fails to identify what specific limitation present in the claims excludes the prior art of record. The underlying mechanism by which diphtheria toxoid works is immaterial to the rejection as the prior art need not explicitly state that which is inherent to the administration of diphtheria toxoid as taught by the instant disclosure. The process steps of the prior art and the instant Application are the same, i.e. the administration of diphtheria toxoid. This process inherently inhibits or reverses ADP-ribosylation, and therefore inherently ameliorates neuronal degeneration. It is immaterial what the intended use is of the diphtheria toxoid of the prior art as the intended use does not bestow a patentable distinction.

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4. Claims 1, 3-5, and 7-8 are rejected under 35 U.S.C. 102(e) as being anticipated by US 2002/0187157 A1 (Jensen et al., "Jensen"). Jensen teaches the use of diphtheria toxoid conjugated to amyloid to induce amyloid downregulation (page 11, paragraph 0126) to treat Alzheimer's disease, a neurodegenerative disease. Jensen also teaches adjuvants (page 12, paragraph 0136), boosters (page 13, paragraph 0157), and injections or oral administration (page 12, paragraph 0137). Also see claims 11, 27, and 33.

Applicant's arguments filed 7/21/03 have been fully considered but they are not persuasive because Applicant fails to identify what specific limitation present in the claims excludes the prior art of record. The underlying mechanism by which diphtheria toxoid works is immaterial to the rejection as the prior art need not explicitly state that which is inherent to the administration of diphtheria toxoid as taught by the instant disclosure. The process steps of the prior art and the instant Application are the same, i.e. the administration of diphtheria toxoid. This process inherently inhibits or reverses ADP-ribosylation, and therefore inherently ameliorates neuronal degeneration. It is immaterial what the intended use is of the diphtheria toxoid of the prior art as the intended use does not bestow a patentable distinction.

5. No claim is allowed.

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO

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MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephen Gucker whose telephone number is (703) 308-6571. The examiner can normally be reached on Monday to Friday from 0930 to 1800. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, can be reached on (703) 308-4623. The fax phone number for this Group is currently (703) 308-4242, but Applicant should confirm this by phoning the Examiner before faxing.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

SG

Stephen Gucker

November 3, 2003

Gary A. Kunz
GARY KUNZ
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600